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09/852,659	05/11/2001	Steven M. Ruben	PZ003P4	5111

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EXAMINER	
PAPPU, SITA S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/04/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/852,659	Applicant(s) RUBEN ET AL.	
	Examiner Sita Pappu	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sh et with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13,17-19 and 24-75* is/are pending in the application.

4a) Of the above claim(s) *1,13 and 17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1, 13, 17-19, 24-75 are pending in the instant application. This Office Action is in response to the Applicant's communication filed on 05/10/2002 in paper # 11. Claim 11 has been cancelled, as requested in paper # 11.

Election/Restrictions

Applicant's election, with traverse, of claims 24-75, directed to the polypeptides encoded by Gene No. 17, is acknowledged. As communicated in the telephone conversation of May 02, 2002, the protein sequence set forth in SEQ ID NO. 85 encoded by Gene No. 17 was assigned to Group 62 and it follows that the amino acid sequence of the second polypeptide encoded by Gene No.17 which is set forth in SEQ ID NO. 68 is assigned to Group 61. Accordingly, Groups 61 and 62 directed to a protein sequence of SEQ ID Nos. 68 and 85, respectively, encoded by Gene No. 17 are being examined, herein, on their merits.

Applicant traversed on the grounds that the new restriction requirement mailed 04/23/2002 was solely done to recast the claim Group numbers via a different Group number (page 4, bottom paragraph) so as to require the election of claims via a different Group number and that the Applicant has previously complied with their duty to provisionally elect and that their previous election complies with the new restriction mailed 04/23/2002. Applicant's arguments are fully considered and in response, Applicant's attention is drawn to claim 11 elected in the previous election (paper #9, 02/15/2002) which is directed to an isolated polypeptide of SEQ ID NO: Y, wherein SEQ ID NO: Y comprises the SEQ ID Nos: 52, 53, 80, 54, 81, 55, 56, 82, 57-60, 83, 61-64,

84, 65-68, 85, 69, 86, 70, 87, 88, 71, 89, 73-75, 91, 76, 77, 92, 78, 79. Thus, claim 11 encompasses the Inventions of groups 40-78. Therefore, the previous election (paper #9) encompasses the Inventions of Groups 40-78 comprising the proteins of SEQ ID Nos: 52, 53, 80, 54, 81, 55, 56, 82, 57-60, 83, 61-64, 84, 65-68, 85, 69, 86, 70, 87, 88, 71, 89, 73-75, 91, 76, 77, 92, 78, 79. Amino acid sequences of different polypeptides are also structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Accordingly, only one (1) independent and distinct nucleotide/polypeptide sequence will be examined in a single application without restriction. The second restriction requirement mailed on 04/23/2002 (paper #10) is directed to among the various polypeptide sequences for prosecution.

Therefore, the restriction requirement mailed on 04/23/02 in paper # 10 is still deemed proper and is made FINAL. Accordingly, claims 1, 13, 17-19 are withdrawn from consideration as being directed to non-elected subject matter. Claims 24-75 are being examined, herein, on their merits.

Priority

Applicant's claim of priority to the following applications is acknowledged. 09/152,060 filed 09/11/1998, 60/265,583 filed 02/02/2001, PCT/US98/04858 filed 03/12/1998, 60/040,762 filed 03/14/1997, 60/040,710 filed 03/14/1997, 60/050,934 filed

05/30/1997, 60/048,100 filed 05/30/1997, 60/048,357 filed 05/30/1997, 60/048,189 filed 05/30/1997, 60/057,765 filed 09/05/1997, 60/048,970 filed 06/06/1997 and 60/068,368 filed 12/19/1997.

However, the isolated protein of SEQ ID NO: 68 or SE ID NO:85 represented by cDNA HPMBQ91 contained in ATCC deposit No. 209070 enjoys support only in the following priority applications: 60/048,357 filed 05/30/1997, PCT/US98/04858 filed 03/12/1998, 60/265,583 filed 02/02/2001.

Double Patenting

Applicant is advised that should claim 24 be found allowable, claim 30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 24 is directed to an isolated protein comprising amino acid residues 19 to 121 of SEQ ID NO:85 while claim 30 is directed to the secreted portion of the polypeptide encoded by the HPMBQ91 cDNA contained in ATCC deposit No. 209070, which in this case refers to amino acid residues 19-121 of SEQ ID NO:85 as disclosed in table 1 of specification on page 58. Thus, claims 24 and 30 have the same scope.

Applicant is advised that should claim 25 be found allowable, claim 31 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both

cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 25 is directed to an isolated protein comprising amino acid residues 2 to 121 of SEQ ID NO:85 while claim 31 is directed to the complete polypeptide encoded by the HPMBQ91 cDNA contained in ATCC deposit No. 209070,excepting the N-terminal methionine, which in this case refers to amino acid residues 2-121 of SEQ ID NO:85 as disclosed in table 1 of specification on page 58. Thus, claims 25 and 31 have the same scope.

Applicant is advised that should claim 26 be found allowable, claim 32 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 26 is directed to an isolated protein comprising amino acid residues 1 to 121 of SEQ ID NO:85 while claim 32 is directed to the complete polypeptide encoded by the HPMBQ91 cDNA contained in ATCC deposit No. 209070, which in this case refers to amino acid residues 1-121 of SEQ ID NO:85 as disclosed in table 1 of specification on page 58. Thus, claims 26 and 32 have the same scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 34, 39, 44, 49, 54, 59, 64, 69, 74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the Invention and the breadth of the claims:

Claims 28, 34, 39, 44, 49, 54, 59, 64, 69, 74 are directed to a composition of the protein of the instant invention as set forth in SEQ ID NO: 85 in a pharmaceutically acceptable carrier. Claims encompass the use of the protein composition for pharmaceutical purposes and for diagnosis and treatment of diseases and conditions of embryonic and reproductive disorders, cancer and Alzheimers disease (page 36, lines 10-17). Thus, the nature of the invention is directed to the use of the protein of the instant invention in protein therapy.

State of the art, Amount of guidance in the specification and working examples:

Prior art (Kotani et al. (1986, Proc. Natl. Acad. Sci., USA, vol. 83, pp. 7074-7078) and the specification (page 35, lines 1-3) teach that the polypeptide of the instant invention shares homology with Preprotachykinin B which is thought to be important in the signal transduction and information processing in the nervous system and that it is expressed in human placenta and to a lesser extent in soares placenta (page 35, lines 24-25). The specification further teaches that the instant neurokinin may modulate smooth muscle or vascularization associated with reproduction (page 35, lines 14-17) and that based on the homology it is likely that the polypeptides of the instant invention are active in the signal transduction and information processing in the nervous system. The specification also teaches that the tissue distribution and homology to preprotachykinin B suggests that the polypeptides of the instant invention are useful for the diagnosis and treatment of reproductive and embryonic disorders and cancer (page 36, lines 10-17), and that they can also be used to treat Alzheimers disease and as tumor markers.

The working examples demonstrate the expression of the polypeptide in E. coli (example 5, page 271), in baculovirus system (example 7, page 274), in mammalian cells (example 8, page 277), production of secreted protein for screening assays (example 11, page 283), and methods of in vitro screening and activity assays (examples 13-20). Example 23 discloses general methods of how formulations may be used. Examples 24-58 disclose a general prophetic discussion of how the polynucleotides and the polypeptides may be used in methods of treatment and therapy

and how transgenic animals may be used as models to study the effects of the polypeptides without any supporting data.

Other than this, the specification fails to provide any specific teachings on how the polypeptide of SEQ ID NO:85 or 68 can be used to diagnose and/or treat any of the diseases or conditions disclosed in the specification. The specification fails to disclose any pharmaceutical property for the polypeptide of the instant invention. Nor does it teach the efficacy of the polypeptide in treating any of the conditions disclosed.

Prior art does not teach use of the polypeptides of the instant invention for the purpose of therapy in mammals and humans to such levels that a therapeutic effect is obtained. In cases where prior art does not teach how to use the method, all the guidance for practicing the invention must come from the specification. The specification fails to disclose therapeutic or pharmaceutical effect for the polypeptide in the cells of mammals and/or humans or in an art recognized animal model, such that one of skill in the art would accept that their method would result in a therapeutic outcome and be able to practice the method using the guidance provided in the specification.

Skill level of the artisan, Predictability of the invention and amount of experimentation necessary:

Patak et al. (2000, Clin. Exp. Pharmacol. Physiol. Vol. 27, pp. 922-927) teach that of the three studied tachykinins (substance P, neurokinin A and neurokinin B), only NKA elicited uterine contraction response in tissue from pregnant women (page 924, left column, first paragraph) and that in tissue from non-pregnant women the responses are

mediated through the NK1 receptor, the receptor for substance P (page 925, left column, paragraph 3). The findings of this study do not indicate any substantial and correlative association of neurokinin B, which is encoded by the preprotachykinin B gene comprising the sequence set forth in SEQ ID NO: 68 or 85 of the instant invention, and reproductive and/or embryonic disorders, cancer and Alzheimers disease. Patak et al. (2000) also state that further research is required on the factors mediating release of tachykins and on their potential interactions with the myriad cell types present in the uterus, particularly throughout pregnancy and during term and preterm labour, before a clear-cut physiological or pathophysiological role for these neuropeptides can be established or rejected. Thus, Patak et al teach that the state of the art, even at post filing date, does not clearly establish an association between preprotachykinin B that encodes neurokinin B and reproductive and embryonic disorders or cancer and Alzheimers disease. In such a situation, it is unpredictable without specific guidance and direction whether one will achieve a pharmaceutical and therapeutic effect using the polypeptide of the instant invention in treating the conditions and disorders contemplated in the specification. When there is deficiency in the art in terms of predictability of obtaining therapeutic levels of expression, the Applicant must provide sufficient guidance and direction which demonstrates or reasonably correlates to therapeutic levels of expression of a DNA product in an art recognized animal model or patient as claimed.

Although the skill of an artisan in this subject area is considered to be very high, it would require undue experimentation on the part of an artisan to make and use the

invention as specified and use the invention as claimed. The specification and the working examples do not provide sufficient guidance to practice the invention as claimed. Therefore, in the absence of specific guidance and working examples, the use of the composition of polypeptide for pharmaceutical purposes is unpredictable. In such a situation, one skilled in the art would not know how to use the invention as claimed, without undue experimentation. In view of the limited guidance in the specification, and limited working examples, and the unpredictability of the art, one skilled in the art would be required to engage in undue experimentation, in order to use the invention. It is noted that the law requires that the disclosure of an application shall inform those skilled in the art how to use applicants' alleged discovery, not how to find out how to use it for themselves (see In re Gardner et al. 166 USPQ 138 (CCPA 1970). The specification only teaches what is intended to be done, but does not actually teach how to do that which is intended.

Thus, due to the art recognized unpredictability of achieving therapeutic outcomes using the pharmaceutical compositions claimed, the lack of guidance provided by the specification, the lack of guidance concerning the treatment of various diseases using the claimed polypeptide of the instant invention, it would have required undue experimentation to practice the instant invention and the skilled artisan would not have predicted success in using the claimed polypeptide in pharmaceutical compositions for diagnosis and/or treatment of the conditions and disorders as disclosed in the specification. Thus the specification does not enable one skilled in the art to use the claimed compositions and methods in protein therapy.

Claims 27, 33, 36-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 27, 33, 38, 43, 48, 53, 58, 63, 68, 73 are directed to a polypeptide that is heterologous to SEQ ID NO: 85. Claims 36-55 are directed to a polypeptide that is 90% or 95% identical to SEQ ID NO: 85. Claims 56-75 are directed to a polypeptide consisting of at least 30 or 50 contiguous amino acid residues of amino acid residues 1 to 121 of SEQ ID NO: 85.

Vas-Cath Inc. v. Mahurkor, 19UGPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" Vas-Cath Inc. v. Mahurkar 19UGPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."Vas-Cath Inc. v. Mahurkar 19UGPQ2d at 1116.

While the specification provides adequate written description for the claimed invention (methods and products) only with regard to the SeqID NO: 85 and/or SEQ ID NO:68, the specification fails to describe the other species within the genus of "polypeptides heterologous to SEQ ID NO: 85 or at least 90% or 95% identical to the polypeptide sequences of SEQ ID NO: 85, or polypeptides consisting of at least 30 or

50 contiguous amino acid residues of amino acid residues 1 to 121 of SEQ ID NO: 85 ". The specification fails to describe a representative number of the sequences encompassed by the said genus by their complete structure and other identifying characteristics, with particularity to indicate that applicants had possession of the claimed invention. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying charecteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc. 45 USpQ2d 1641, 1646 (1995). In the instant case, the claimed embodiments of sequences other than those of SEQ ID NO:85 or 68, lack a written description. The specification fails to describe what elements other than those isolated from human, fall into this genus. The skilled artisan cannot envision the detailed chemical structure of an of the encompassed sequences isolated from other species, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Lfd, 18 USPQ2d 1016 (Fed. Cir. 1991).

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. However, in the instant case, two specific polypeptide

sequence species (SEQ ID NO:85 or 68, the latter being a variant of SEQ ID NO: 85) are described. However the claims encompass all sequences that are heterologous to SEQ ID NO: 85 or at least 90% or 95% identical to SEQ ID NO: 85 or polypeptides consisting of at least 30 or 50 contiguous amino acid residues of amino acid residues 1 to 121 of SEQ ID NO: 85. Thus, the specification must describe a representative number of the encompassed species by their complete structure. Next then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. In this case, since structure and/or function cannot be predicted from sequence, no identifying characteristics are provided for the claimed genus of sequences. This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of all the sequences that are encompassed by the claims, at the time the application was filed. Thus, it is concluded that the written description requirement is not satisfied for the claimed sequences and polypeptides.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-27, 29-35, 38, 41-44, 48, 53, 58, 63, 68, 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite in its recitation of "comprising amino acid residues 19 to 121 of SEQ ID NO:85". Use of claim language such as "comprising the sequence set

forth in SEQ ID NO:85 from residues 19 to 121" is suggested. Claims 25-29 are rejected insofar as they depend from claim 24.

Claims 25 and 26 are indefinite in that they fail to further limit the subject matter of claim 24 from which they depend.

Claims 30, 41 are indefinite in their recitation of "secreted portion of the polypeptide encoded by the HPMBQ91 cDNA contained in ATCC deposit No. 209070". It is not clear what the Applicant is referring to. Table 1 of the specification on page 58 discloses two secreted polypeptides. The secreted portion of SEQ ID NO: 68 of ATCC Deposit No. 209070 comprises the amino acids 17-121, while the secreted portion of SEQ ID NO: 85 of ATCC Deposit No. 209070 comprises the amino acids 19-121. Correction or clarification is required. Claims 31-35 are rejected insofar as they depend from claim 30. Claims 42-44 are rejected insofar as they depend from claim 41.

Claim 31 is indefinite in its recitation of "complete polypeptide encoded by the HPMBQ91 cDNA contained in ATCC deposit No. 209070, excepting the N-terminal methionine". Claim 31 fails to further limit the subject matter of the claim 30 from which it depends. Claim 30 is directed to only the secreted portion of the polypeptide encoded by the HPMBQ91 cDNA contained in ATCC deposit No. 209070 (i.e., 19-121 residues of the polypeptide), while claim 31 is directed to the complete polypeptide, excepting the N-terminal methionine (residues 2-121) encoded by the HPMBQ91 cDNA contained in ATCC deposit No. 209070.

Claim 32 is indefinite in its recitation of "complete polypeptide encoded by the HPMBQ91 cDNA contained in ATCC deposit No. 209070,". Claim 32 fails to further limit

the subject matter of the claim 30 from which it depends. Claim 30 is directed to only the secreted portion of the polypeptide encoded by the HPMBQ91 cDNA contained in ATCC deposit No. 209070 (i.e., 19-121 residues of the polypeptide), while claim 32 is directed to the complete polypeptide (residues 1-121) encoded by the HPMBQ91 cDNA contained in ATCC deposit No. 209070.

Claims 27, 33, 38, 43, 48, 53, 58, 63, 68, 73 are indefinite in their recitation of "a polypeptide sequence heterologous to SEQ ID NO:85". The term "heterologous" is usually used to refer to a gene or protein which is being expressed in an organism or cell in which it is not normally present. The context in which the term is used in the instant claims and how two sequences can be heterologous to each other is not clear.

Conclusion

The claims are free of the prior art of the record.

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308 4242 for regular communications and (703) 872 9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Anne-Marie Baker

ANNE-MARIE BAKER
PATENT EXAMINER

S. Pappu
May 31, 2002